CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

UNITED STATES OF AMERICA,) Plaintiff,)	Civil No. AO7CA 996SS
v. ,	
THOMAS L. CROFUT and) JUDITH H. CROFUT,) individuals d/b/a)	
GOOD FLOW HONEY AND JUICE CO.,)	COMPLAINT FOR PERMANENT INJUNCTION
Defendants.)	

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

- 1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the inherent authority of this Court, to enjoin and restrain Thomas L. Crofut and Judith H. Crofut, (collectively, "Defendants"), individuals doing business as Good Flow Honey and Juice Co. ("Good Flow"), from violating 21 U.S.C. § 331(k) by causing any food that is held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).
- 2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345. Venue in this district is proper under 28 U.S.C. §§ 1391(b).

THE DEFENDANTS

- 3. Defendants Judith H. Crofut and Thomas L. Crofut are co-owners of Good Flow, an unincorporated proprietorship.

 Defendants receive, process, prepare, pack, hold, and distribute unpasteurized fresh-squeezed fruit and vegetable juices and juice blends ("juice") at their juice production facility at 2601 East Cesar Chavez Street, Austin, Texas. Defendants' juice is "food" within the meaning of 21 U.S.C. § 321(f).
- 4. Defendants conduct juicing operations six days per week and employ eight to ten people, depending on daily demand.

 Defendants' juices are made from a variety of fruits that are shipped in interstate commerce. For example, Defendants receive lemons and oranges from a supplier in California, apples from a supplier in Washington, and limes that are imported from Mexico. Additionally, Defendants' finished juices are packaged in plastic bottles made in Venezuela using bottle closures from Kentucky.
- 5. Defendant Judith H. Crofut is responsible for the dayto-day management of Good Flow's juice production facility,
 including the supervision and training of employees. She has
 represented Good Flow during inspections by the Food and Drug
 Administration ("FDA") of the firm's juice production facility,
 and has corresponded with FDA both orally and in writing
 following such inspections. Her signature also appears on the

firm's Operations Manual and Hazard Analysis and Critical Control Point ("HACCP") Plan.

6. Defendant Thomas L. Crofut makes all operational decisions concerning Good Flow jointly with Defendant Judith H. Crofut. He helped draft and signed the firm's Operations Manual and HACCP Plan. He has also signed several letters to FDA following FDA inspections of Good Flow's juicing operations.

UNPASTEURIZED JUICE SAFETY

- 7. Unpasteurized, fresh-squeezed juice is a high-risk food that has been shown to be a source of Salmonella and other bacterial pathogens. Exposure to Salmonella can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems.

 Otherwise healthy individuals may suffer short-term symptoms such as high fever, severe headache, vomiting, nausea, abdominal pain, and diarrhea. Long-term complications can include severe arthritis.
- 8. The production of juice without proper monitoring and sanitation controls creates optimal conditions for the proliferation of Salmonella and other pathogenic microorganisms.

REGULATORY FRAMEWORK

9. In order to minimize potential contamination hazards known to occur during the juice manufacturing process, producers

must follow the juice HACCP regulations found in 21 C.F.R. Part 120.

- must conduct, or have conducted for it, a hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur during the processing of each kind of juice that it produces. 21 C.F.R. § 120.7(a). Whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur, such processor must, pursuant to 21 C.F.R. § 120.8(a), have and implement an adequate written HACCP plan to control the identified food safety hazard(s).
- 11. A HACCP plan must identify critical control points, which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to acceptable levels, a food safety hazard. 21 C.F.R. §§ 120.3(d), 120.7(a)(5).
- 12. At each critical control point, a HACCP plan must also identify critical limits, which are the maximum or minimum values to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). 21 C.F.R. §§ 120.3(e), 120.8(b)(3).
- 13. The HACCP regulations specifically require processors of unpasteurized juice to include control measures in their HACCP

plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganism of public health significance likely to occur in the juice. 21 C.F.R. § 120.24(a).

- required to use a treatment process that is applied directly to the juice. 21 C.F.R. § 120.24(b). However, citrus juice processors may use a 5-log reduction process that is applied to the surface of the fruit as opposed to the juice. Id. If a 5-log reduction process is used that does not come into contact with all parts of the juice, the processor must analyze the finished juice for biotype I Escherichia coli ("E. coli"). See 21 C.F.R. § 120.25. The presence of E. coli in processed juice is an indicator of possible Salmonella contamination. E. coli is also a potential human health risk in its own right because certain strains of the bacteria are pathogenic and can cause diarrhea, vomiting, and even death, especially in young children, frail or elderly people, and others with weakened immune systems.
- 15. The HACCP regulations further require that juice processors monitor and record sanitation conditions and practices during juice processing to ensure conformance with current Good Manufacturing Practices ("CGMP"). 21 C.F.R. §§ 120.5-.6.
- 16. Each juice processor must verify that its HACCP plan is adequate to control food safety hazards that are reasonably

likely to occur, and that the plan is being effectively implemented. 21 C.F.R. § 120.11(a)-(b).

17. Juice products that are processed without adhering to the requirements of 21 C.F.R. Part 120 are adulterated under 21 U.S.C. § 342(a)(4). 21 C.F.R. § 120.9.

DEFENDANTS' CONDUCT AND VIOLATIONS

- 18. Defendants violate 21 U.S.C. § 331(k) by causing juice to become adulterated after shipment in interstate commerce.
- 19. Defendants' juice is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, processed, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.
 - 20. Defendants have failed to, and continue to fail to:
- (a) include control measures in their HACCP plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganism of public health significance likely to occur in unpasteurized, fresh-squeezed citrus juice, 21 C.F.R. § 120.24(a);
- (b) monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP, 21 C.F.R. § 120.6(b);
- (c) maintain records that, at a minimum, document their monitoring and correction of sanitation conditions and practices, 21 C.F.R. S 120.6(c); and

(d) prepare, process, pack and hold their juice under appropriate conditions to avoid the adulteration of their products.

DEFENDANTS' HISTORY OF VIOLATIONS

March 2007 Inspection

- 21. FDA has inspected Defendants' plant on three occasions. During an inspection from March 12-21, 2007, FDA observed serious deficiencies in Defendants' HACCP plan, their implementation and verification of that plan, and their sanitation practices. Many of these deficiencies had been observed during previous inspections. The most significant repeated deficiencies include, but are not limited to, the following:
- (a) Defendants failed to include control measures in their HACCP plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganisms of public health significance that are likely to occur in their juices.

 See 21 C.F.R. § 120.24. For example, although the pathogens E. coli, Cryptosporidium parvum, and Listeria monocytogenes ("L. mono.") are associated with apple juice, Clostridium botulinum and E. coli are associated with carrot juice, and Salmonella, L. mono. and E. coli are associated with strawberry and orange juices, Defendants' HACCP plan does not include control measures to consistently produce a 5-log reduction in any of these

pathogens. This was a repeat violation that FDA had observed in previous inspections.

- (b) Defendants failed to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP. See 21 C.F.R. § 120.6(b). Specifically, defendants failed to monitor with sufficient frequency the prevention of cross-contamination from insanitary objects, as evidenced by instances where: (1) unwashed fruit, including moldy fruit, was sliced and placed into tubs of water before being juiced, a practice that exposes the flesh of the fruit, and subsequently the juice, to potential contaminants that may be present on the fruit's peel; (2) an employee wore gloves while handling and discarding moldy fruit, and then cut fruit used to make juice while wearing the same gloves; and (3) a spray nozzle soiled with fruit pulp and other debris was placed into a tub containing water and cut fruit that was subsequently processed into juice. See 21 C.F.R. § 120.6(a)(3). Defendants also failed to monitor with sufficient frequency the condition and cleanliness of food contact surfaces, as evidenced by defendants' use of a discolored and scored cutting board, soiled plastic shovel, gloves that had been in contact with soiled plastic door flaps, and a knife whose handle was wrapped with a soiled white bandage tape. See 21 C.F.R. § 120.6(a)(2).
 - (c) Defendants failed to maintain records that, at a

minimum, document their monitoring and correction of sanitation conditions and practices. <u>See</u> 21 C.F.R. S 120.6(c). Specifically, the firm's "Daily Log" with respect to sanitation practices was not filled in during several days when juice was being produced.

August/September 2006 Inspection

22. FDA conducted a previous inspection of Defendants' operations between August 28 and September 7, 2006. During this inspection, FDA investigators observed numerous HACCP violations, nearly all of which were noted again in the March 2007 inspection. The inspection found, for example, that Defendants' HACCP plan was insufficient to obtain the required 5-log reduction in the pathogens associated with the various juices manufactured by the firm; Defendants failed to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP; and Defendants failed to maintain records that, at a minimum, document their monitoring and correction of SSOP conditions and practices. This inspection resulted in a Warning Letter being issued to Defendants on January 24, 2007.

September 2003 Inspection

23. A previous inspection conducted by FDA on September 18, 2003 found, among other things, that Defendants had failed to develop a written hazard analysis to determine whether there are

food hazards that are likely to occur; Defendants had no written HACCP plan for the processing of juice; and Defendants had no records documenting their monitoring and correction of sanitation practices conditions and practices. This inspection resulted in the FDA issuing a letter to the Defendants on May 24, 2004 outlining deficiencies observed and encouraging necessary improvements.

PRIOR NOTICE

- 24. Defendants have received ample notice that their juice processing operations violate the law and that continued violations could lead to regulatory action. At the close of the September 2003, August/September 2006, and March 2007 inspections, FDA investigators issued Forms FDA-483 List of Inspectional Observations ("Forms 483") to Defendant Judith Crofut, that notified Defendants of the investigators' observations. FDA investigators also discussed their observations with Defendant Judith Crofut and encouraged her to make necessary corrections.
- 25. In addition, FDA sent Defendants a letter following the September 2003 inspection noting observed deficiencies and a Warning Letter following the September 2006 inspection.
- 26. In response to the inspections and Warning Letter,
 Defendants have repeatedly promised to bring their facility into
 full compliance with regulatory requirements. Following the

September 2003 inspection, Defendant Thomas Crofut promised to correct all deficiencies, and noted that the firm was "working diligently" to achieve compliance with the juice HACCP requirements. In response to the August/September 2006 inspection, Defendant Judith Crofut promised to correct the noted deficiencies, but expressed concern about the "financial risk[s]" associated with equipment upgrades. After receiving the Warning Letter in January 2007, Defendants stated that the firm intended to "fully comply with HACCP" but was in the process of "redefining" to bring the firm "in line with 21st century realities." Following the March 2007 inspection, Defendant Judith Crofut promised corrections and acknowledged the firm's need to comply with the 5-log reduction requirement. However, she noted that the process was "complicated" and "could easily take two years."

- 27. Despite multiple inspections by FDA, and Defendants' promises that violations would be corrected, Defendants have failed to institute effective measures to bring their juice processing operations into compliance with the law.
- 28. The United States is informed and believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

WHEREFORE, the United States respectfully requests that this Court:

- I. Permanently and restrain and enjoin Defendants Thomas L. Crofut and Judith H. Crofut, individuals, and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's order, from violating 21 U.S.C. § 331(k) by directly or indirectly causing any article of food, within the meaning of 21 U.S.C. § 321(f), to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce.
- II. Order Defendants Thomas L. Crofut and Judith H. Crofut, individuals, and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's order, to cease receiving, processing, preparing, packing, holding, and distributing all juice at or from their plant, or at any other location(s) from which Defendants receive, process, prepare, pack, hold, or distribute food, unless and until:
- A. Defendants bring their receiving, processing, preparing, packing, holding, and distribution operations into

compliance with the Act and its implementing regulations to the satisfaction of FDA;

- B. Defendants destroy all adulterated food currently held in their plant according to procedures approved by and under the supervision of FDA;
- C. Defendants establish and implement adequate written HACCP plans, developed by an independent juice HACCP expert and approved in writing by FDA, that are sufficient to control food safety hazards likely to occur in the processing of each type of juice processed by Defendants, as required by 21 C.F.R. §§ 120.7 and 120.8;
- D. Defendants have an independent juice HACCP expert validate the adequacy of control measures in Defendants' HACCP plans to consistently produce, at a minimum, a 5-log reduction in the most resistant organism of public health significance that is likely to occur in each juice, as required by 21 C.F.R. § 120.24, and the results of the validation study have been admitted to and approved in writing by FDA;
- E. To the extent Defendants utilize in their production of citrus juice a surface treatment process to achieve a 5-log reduction of the most resistant organism of public significance, Defendants analyze their unpasteurized, finished citrus juice products for *E. coli* in accordance with the frequency and methods of analysis prescribed in 21 C.F.R. § 120.25;

F. Defendants have accomplished all of the above to FDA's satisfaction and have been so notified by FDA in writing.

III. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated this _____ day of December, 2007.

Respectfully submitted,

OF COUNSEL:

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SJS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS			DEFENDANTS	DEFENDANTS		
United States of America			Thomas L. Crofut, Judith H. Crofut, d/b/a Good Flow Honey and Juice Co.			
(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)			County of Residence of	County of Residence of First Listed Defendant Travis County (IN U.S. PLAINTIFF CASES ONLY)		
(EXCEPT IN U.S. PLAINTIFF CASES)			NOTE: IN LAND	NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE		
		·		NVOI VED		
(c) Attorney's (Firm Name, Address, and Telephone Number)			Attorneys (If Known)	AU7CA	996 SS	
David Sullivan, Department of Ju- Washington, D.C. 20044	stice, PO Box 386, 1331 Pennsylvania Ave	., N.W., Room 950 N.,		•		
II. BASIS OF JURISD	ICTION (Place an "X" in One Bo	x Only) III. C		RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff	
■ 1 U.S. Government Plaintiff □ 3 Federal Question (U.S. Government Not a Party)		arty) Citi	(For Diversity Cases Only) PTF DEF Citizen of This State 1 1 1 Incorporated or Principal Place of Business In This State and One Box for Defendant) PTF DEF Of Business In This State			
2 U.S. Government	☐ 4 Diversity	Citi	izen of Another State	2	Principal Place 5 5 5	
Defendant	(Indicate Citizenship of Par	rties in Item III)		of Business In	Another State	
			Citizen or Subject of a			
IV. NATURE OF SUIT	(Place an "X" in One Box Only) TORTS		RFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
□ 110 Insurance			610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment	
☐ 120 Marine	☐ 310 Airplane ☐ 36	52 Personal Injury -	620 Other Food & Drug	423 Withdrawal	410 Antitrust	
☐ 130 Miller Act ☐ 140 Negotiable Instrument	☐ 315 Airplane Product Liability ☐ 36	Med. Malpractice 5 Personal Injury -	625 Drug Related Seizure of Property 21 USC 881	28 USC 157	430 Banks and Banking 450 Commerce	
☐ 150 Recovery of Overpayment	☐ 320 Assault, Libel &	Product Liability	630 Liquor Laws	PROPERTY BY	460 Deportation	
& Enforcement of Judgment 151 Medicare Act	Slander		640 R.R. & Truck 650 Airline Regs.	☐ 820 Copyrights ☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations	
☐ 152 Recovery of Defaulted	Liability		660 Occupational	☐ 840 Trademark	480 Consumer Credit 490 Cable/Sat TV	
Student Loans (Excl. Veterans)		SONAL PROPERTY 0 Other Fraud	Safety/Health 690 Other		490 Cable/Sat TV 810 Selective Service	
☐ 153 Recovery of Overpayment of Veteran's Benefits		1 Truth in Lending 0 Other Personal	LABOR 710 Fair Labor Standards	SOCIAL SECURITY 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange	
160 Stockholders' Suits	☐ 355 Motor Vehicle	Property Damage	Act	☐ 862 Black Lung (923)	☐ 875 Customer Challenge	
☐ 190 Other Contract ☐ 195 Contract Product Liability	Product Liability 38		720 Labor/Mgmt. Relations 730 Labor/Mgmt.Reporting	☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI	12 USC 3410 ☐ 890 Other Statutory Actions	
☐ 196 Franchise	Injury		& Disclosure Act	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts	
REAL PROPERTY 210 Land Condemnation			740 Railway Labor Act 790 Other Labor Litigation	FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff	892 Economic Stabilization Act 893 Environmental Matters	
220 Foreclosure	442 Employment	Sentence	791 Empl. Ret. Inc.	or Defendant)	☐ 894 Energy Allocation Act	
230 Rent Lease & Ejectment 240 Torts to Land		abeas Corpus: 0 General	Security Act	26 USC 7609	895 Freedom of Information Act	
245 Tort Product Liability	☐ 444 Welfare ☐ 53	5 Death Penalty		20 000 1009	900Appeal of Fee Determination	
290 All Other Real Property		0 Mandamus & Other 0 Civil Rights			Under Equal Access to Justice	
	☐ 446 Amer. w/Disabilities - ☐ 55				☐ 950 Constitutionality of	
	Other 440 Other Civil Rights				State Statutes	
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VI. CAUSE OF ACTION	Cite the U.S. Civil Statute ur 21 U.S.C. 331(k)			al statutes unless diversity):		
	Brief description of cause: To enjoin Defendant fr	om selling adulterat	ted food.		.	
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS IS A C UNDER F.R.C.P. 23	CLASS ACTION 1	DEMAND \$	CHECK YES only JURY DEMAND:	if demanded in complaint:	
VIII. RELATED CASI	E(S) (See instructions): JUDG	SF.		DOCKET NUMBER		
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DATE	SI	GNATURE OF ATTORNEY	Y OF RECORD) .		
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RECEIPT # A	MOUNT	APPLYING IFP	JUDGE	MAG. JUI	OGE	